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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/858,035      | 05/15/2001  | Tarun J. Edwin       | 297912001911        | 4383             |

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EXAMINER

PREBILIC, PAUL B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|          | 3738         |

DATE MAILED: 07/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                                |
|------------------------------|-----------------|--------------------------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)                   |
|                              | 09/858,035      | EDWIN ET AL. <i>(initials)</i> |
| Examiner                     | Art Unit        |                                |
| Paul B. Prebilic             | 3738            |                                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 20 May 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 41-50 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 41-50 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.8. 6) Other:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45, 47, 48, and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 45, line 3, the Examiner asserts that "spring metal alloys" lacks original support; see page 10, lines 4-11 of the specification.

Claims 47 and 48 lack original support where only overlapping polymer layers with no additional inner and outer tubular elements is originally disclosed; see page 14, line 28 to page 15, line 3 of the specification. Therefore, the claimed invention lacks original support because it is claiming a combination of species that was not originally disclosed.

The language of claim 50 "generally quadrilateral cross-section" lacks original support because, the original specification did not set forth how broadly to interpret the term "generally." For this reason, the claim scope is beyond the original meaning of what was disclosed therein; see MPEP 2173.05(b), which is incorporated herein by reference. The specification fails to provide some standard for measuring that degree.

Therefore, one of ordinary skill would not know what degree of "generally" would fall within the claim scope and what would not.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45, 47, 48, and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 45 and as an alternative to the Section 112, first paragraph rejection above, it is not clear, but original claim 2 may give support to the terminology "spring metal alloys" as claimed. If it can be shown to give support to the claimed subject matter, then the specification would have to be amended in order to give antecedent basis to this subject matter from the specification.

With regard to claims 47 and 48 and as an alternative to the Section 112, first paragraph rejection above, it may be that the combination of species has implicit support. If so, then the claims are indefinite because they lack clear antecedent support from the specification.

With regard to claim 50, the claim language is considered to be indefinite because the scope of "generally quadrilateral cross-section" has an unclear scope as described in the Section 112, first paragraph rejection above.

### ***Claim Objections***

Claim 48 is objected to because of the following informalities:

In claim 48, line 2, "comprises" is grammatically awkward and should be changed to ---comprise--- instead. Appropriate correction is required.

***Interference***

The Examiner would like to note the similar scope of the present claims as compared to claim 2 of US Patent Number 6,364,904. Although the present claims are unpatentable over prior art, the potential exists for the present claims to be close enough in scope to that of the patented claims such that an interference would have to be declared.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41, 42, and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,264,684. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more detailed and narrower in scope than that of the present claims such that they are read on thereby.

Therefore, the present claims are considered to be obvious over the patented claims under double patenting doctrine.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 41, 42, 44, and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Pinchuk et al (US 5,968,091). Pinchuk anticipates the claim language where the elongate support member as claimed is the wire stent (30) of Pinchuk; see (130) Figure 7. In addition, the polymer cladding as claimed is met by the polycarbonate urethane coating of Pinchuk which overlaps at adjacent zigzags (34, 36) and are joined thereat; see column 5, lines 40-55 and column 2, line 55 to column 3, line 2.

With regard to claim 44, Applicant is directed to column 3, lines 21-52. Also, polycarbonate polyurethane is a type of polyurethane as claimed.

With regard to claim 45, ELIGLOY of Pinchuk is a shape memory alloy as claimed and tantalum is a type of biocompatible spring metal alloy as claimed; see Examples 9 and 12 of Pinchuk.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al (US 5,968,091) in view of Dotter (US 4,503,569). Pinchuk discloses materials that have a resilient or general shape memory property but fails to disclose a clear teaching a shape memory material with an austenitic state as claimed. However, Dotter teaches that it was known to use austenitic state shape memory materials in the art; see the abstract, the figures, and column 4, lines 25-40. Hence, it is the Examiner's position that it would have been obvious to use austenitic state shape memory materials in the Pinchuk invention so as to more precisely control the expansion of the stent and for the same reasons that Dotter uses the same.

Claims 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al (US 5,968,091) in view of Lee (US 5,123,917).

With regard to claims 47 and 48, Pinchuk fails to disclose an inner and outer tubular substrate as claimed. However, Lee teaches that it was known to use inner and outer tubular substrate with similar stents; see Figures 1, 2, 6, and 7 as well as column 4, line 41 to column 5, line 55. Therefore, it is the Examiner's position that it would have been obvious to use inner and outer tubular substrates on the Pinchuk stent for the

same reasons as Lee and in order to provide a smoother surface along the blood flow path, thus preventing or reducing thrombosis.

With regard to claims 49 and 50, Pinchuk fails to disclose a wire member in planar ribbon form or a polymer cladding in quadrilateral cross-section as claimed. However, Lee teaches that it was known to form stents in planar or cylindrical form; see Figures 1 and 2 and compare with Figures 6 and 7. Hence it is the Examiner's position that it would have been obvious to form the wire of Pinchuk in a planar form in order to provide a lower profile, and thus, lower thrombogenic device than with a cylindrical wire member. If a planar wire member was used in Pinchuk, the coating thereover would be in a quadrilateral configuration as claimed since it would coat a quadrilateral substrate.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

  
Paul Prebilic  
Primary Examiner  
Art Unit 3738